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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,950	08/17/2000	Josef Burg	HUBR-1159	9456
24972	7590	04/20/2004	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			AUDET, MAURY A	
			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,950

Applicant(s)

BURG ET AL.

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 88-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 88-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Arguments/Amendment

This action is in response to the papers filed 01/20/2004 and 1/22/2004. Claims 88-104 are pending.

Claim Rejections - 35 USC § 102

The rejection of claims 88-104 under 35 U.S.C. 102(b) as being anticipated by any of Watson et al. (Glycobiology, 1994, 4(2): 227-37), Takeuchi et al. (Proc. Natl. Acad. Sci., October 1989, 86: 7810-7822), Blumen et al. (US 5,459,031), Akamatsu et al. (US 4,745,099), and Strickland et al. (5,856,298) is maintained for the reasons of record. Applicant's arguments have been fully considered but they are not persuasive. Applicant has argued that “[i]nherency only applies when all features of a claim result inevitably from the prior art. One cannot tell from any of Watson, Takeuchi, Blumen, Akamatsu, or Strickland what percentage of the EPO molecules contain N-acetyllactosamine” (emphasis added). However, Applicant has not clearly shown that the EPO from CHO cells of these references **cannot** have at least 30% repeating N-acetyllactosamine (or/and tetraantennary branches). Thus, absent clear and convincing evidence to the contrary, since these references teach the core components of EPO from CHO cells, they would inherently do/could contain at least 30% repeating N-acetyllactosamine (or/and tetraantennary branches). Furthermore, as discussed in the International Preliminary Examination Report of Applicant's International Application, corresponding to this case, it was discussed in § V.2.2.¶1,:

that recombinant EPO from CHO cells contains 82% tetraantennary oligosaccharides . . . which contain between 4 and 7 (i.e. an average of 5.5) N-acetyl lactosamine units,

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based on a N-bound carbohydrate chain (cf. Table II). The known EPO composition is therefore prejudicial to the novelty of all the independent product claims . . . [and the] dependent claims . . . do not define any features which distinguish the claimed composition from those in the prior art either (emphasis added).

Although the Examining Authority was referring to the Watson et al. reference, as cited above, the same teachings apply to all the references, since all teach EPO from CHO cells.

Applicant has also argued that “[w]hereas some references, e.g., Blumen and Strickland discuss sialic acid content, such is not N-acetylglucosamine content, and one cannot “bootstrap” from the other.” Applicant's further arguments as to Blumen and Strickland have been fully considered but they are not persuasive. Namely, no “bootstrapping” was engaged in by the Examiner. The fact that Blumen and Strickland also discuss another aspect (sialic acid content) of the EPO composition derived from CHO cells, does not change the fact that both references teach the base composition (EPO from CHO cells), as discussed above.

The rejection of claims 88-104 under 35 U.S.C. 102(b) as being anticipated by Nimtz et al. (Eur. J. Biochem., 1993, 213: 39-56) has been dropped since Nimtz et al. is directed to EPO from BHK cells, instead of CHO cells or human cells.

Claim Rejections - 35 USC § 103

The rejection of claims 88-104 under 35 U.S.C. 103(a) as being unpatentable over Watson et al. (Glycobiology, 1994, 4(2): 227-37), Takeuchi et al. (Proc. Natl. Acad. Sci., October 1989, 86: 7810-7822), Blumen et al. (US 5,459,031), Akamatsu et al. (US 4,745,099), or Strickland et al. (5,856,298) in view of EP-A-0 267 678 (Integrated Genetics, Inc.) is maintained for the reasons of record. Applicant's arguments have been fully considered but they

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are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Applicant has only traversed the teachings of the primary references, which the Examiner has maintained above (minus Nimtz et al.). Since the primary references have been maintained, it is still maintained that it would have been obvious, even if not expressly taught, to arrive at an EPO from CHO cells composition, from a serum-free medium, containing at least 30% repeating N-acetyllactosamine (or/and tetraantennary branches), because (EP-A-0 267 678) teach the advantageous use of a serum-free medium in EPO production and since the base components of EPO from CHO cells are taught by the primary references.

Additionally, Applicant argues that "Examiner alleges that routine optimization could produce the claimed invention, but does not show this." Applicant's arguments have been fully considered but they are not persuasive. Applicant has not clearly shown that the EPO from CHO cells of these references **cannot** have at least 30% repeating N-acetyllactosamine (or/and tetraantennary branches).

Claims 88-101, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson et al. (Glycobiology, 1994, 4(2): 227-37), Takeuchi et al. (Proc. Natl. Acad. Sci., October 1989, 86: 7810-7822), Blumen et al. (US 5,459,031), Akamatsu et al. (US 4,745,099), or Strickland et al. (5,856,298).

All the references are discussed above.

If not expressly or intrinsically taught in the above references, it would have been obvious to one of skill in the art at the time the invention was made that at least 30% repeating N-acetylactosamine (or/and tetraantennary branches) in the EPO compositions of any of the references above was/could be obtained, because each of the references teach the base components of EPO from CHO cells. Furthermore, the chemical addition of further repeating units, if desired, on the existing structure is well within the purview of the skilled artisan working in EPO composition manufacturing from CHO cells.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In line with the references above, Takeuchi et al. #2 (Glycobiology. 1991 Sep;1(4):337-46. Review) also teach EPO from CHO cells, including repeating tetraantennary units (see e.g. Table I, CHOb; entire document).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, April 17, 2004


CHRISTOPHER H. TATE
PRIMARY EXAMINER